TWENTY-EIGHTH REGULAR SESSION
October 24-26, 2000
Port of Spain, Trinidad and Tobago

OEA/Ser.L/XIV.2.28
CICAD/doc.1084/00
17 October 2000
Original: Spanish

PROPOSAL FOR THE CONTROL OF THE RAW MATERIALS, INGREDIENTS, AND PRECURSORS USED TO MANUFACTURE CONTROLLED MEDICINES

(Proposal of the Government of Colombia)

PROPOSAL FOR THE CONTROL OF THE RAW MATERIALS, INGREDIENTS, AND PRECURSORS USED TO MANUFACTURE CONTROLLED MEDICINES
Proposal of the Government of Colombia
Inter-American Drug Abuse Control Commission
October 24 to 27, 2000, Trinidad and Tobago
XXVIII Regular Session

Rationale

Bearing in mind human needs in the world to manage pain and other pathologies, the handling of narcotics and psychotropic substances must be regulated in a way that guarantees that the real needs of the ill, whose quality of life would be dramatically affected if these medicines were not available, are met.1

Only since the 1960s, through the end of the 1980s, have regulations been passed on the handling of raw materials and basic substances subject to international control. The objective of these standards was not only to regulate their trade but also to ensure that adequate stocks of controlled medicines were available to meet health care needs, thus enhancing and improving the quality of life of patients who require these medications.

Although controls are in place and ever more states are complying with the provisions of the international conventions to control both international trade and domestic distribution, there continues to be domestic diversion in both producing and importing countries. In addition, smuggling has become the mode, *par excellence,* for bringing controlled substances into other countries.

Statistics show that internal control mechanisms (both on international trade and national distribution) have weaknesses that hinder the full and effective control of these products. One such weakness is the lack of information and lack of coordination of the different controls implemented in each country. Hence, administrative, law enforcement, and penal controls are exercised in an isolated and often parallel manner.

Therefore, the handling of information on illicit trade and the meeting of the real needs of the countries and end users (patients, physicians, and scientists) must be improved, by using an on-line information system that incorporates all data available to the countries in the Hemisphere on licit transactions involving substances.

1 It should be noted here that the preambles to the 1961 Convention on Narcotic Drugs and the 1971 Convention on Psychotropic Substances stress the health stance taken in these instruments, unlike the 1988 UN Convention against Illicit Traffic in Narcotics Drugs and Psychotropic Substances, which is clearly geared towards suppressing and controlling internationally-controlled substances.

PROPOSAL

Pursuant to the provisions of existing multilateral and bilateral instruments, the control and monitoring of internationally-controlled substances, requires systematic evaluation of the movement of these substances.

To that end, Colombia, through the National Narcotics Fund (FNE) -- the central authority responsible for compliance with the provisions of the Conventions of 1961, 1971, and 1988 (Schedule I) -- is proposing the establishment of an information system for controlling **the raw materials, ingredients, and precursors used to manufacture medicines subject to special controls.**[2]

In exercise of the principles and recommendations in the Anti-drug Strategy in the Hemisphere,[3] the information system, as a pilot program, will collect information on the control and monitoring of the movement of substances subject to international controls that are intended for medical and scientific purposes or essentially pharmaceutical uses.

The system must include the evaluation variables established in the International Narcotics Control Board (INCB) questionnaires and forms[4] that each country fills out monthly, quarterly, semiannually, and annually, referring primarily to the movement of internationally-monitored raw materials that are used exclusively by the pharmaceuticals industry to produce controlled medicines.[5]

Furthermore, the system must be on line, to facilitate the addition of information on the manufacture and marketing of controlled medicines in real time. The data must be consistent with the enforcement of existing surveillance mechanisms, such as pre-notifications for the handling of precursor substances in Schedule I of the 1988 Convention,[6] and must be geared towards fulfilling the provisions of the CICAD Model Regulations.

A system that reports in real time on the movement of internationally-monitored substances strengthens national capacity to provide an inter-sectoral response to the potential diversion of pharmaceuticals.

By enabling an exchange of information with judicial authorities in order to conduct joint raids in real time and making the system dynamic in and of itself and with outside users, the system will help strengthen national agencies that control licit aspects of the distribution and use of narcotics and psychotropic substances for pharmaceutical use vis-à-vis the irregular movement of these products.

---

2 This refers to substances controlled internationally, through their inclusion on the schedule of substances in the 1961 Single Convention on Narcotic Drugs and the 1971 Convention on Psychotropic Substances and Schedule I of the 1988 UN Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances. It also takes into account raw materials and finished medicines that have been included on other lists, through bilateral agreements signed between countries in the Hemisphere.

3 In particular subparagraphs 31, 32, 33, and 36.

4 The existing questionnaires and reports must be incorporated into the instrument established based on this proposal or adapted to information-collection needs for the control of pharmaceuticals exclusively.

5 However, it should be borne in mind that piperonal (heliotropine) – Schedule I of the 1988 Convention– is used by industry for dying or flavoring – a variable not applicable to the pharmaceuticals industry. It should be mentioned that the FNE specifically inspects and control laboratories and distributors that use this substance, in order to keep the database current and conduct on-site checks of the conditions required by the laws governing their handling. Inspection findings can be requested from the National Narcotics Fund Office.

6 In other words, Article 12 of the 1988 Convention is implemented to the fullest extent.

Given the above, an exchange of documents on the penal and administrative sanctions levied in each country is essential. The system will be a source of administrative information and will also facilitate law enforcement and judicial efforts. To this end, it must be possible to add information to the system and for it to be updated on legislative progress made in and by the countries that contribute to the information-collection system.7

In a later stage, the information system must become a tool that guarantees the exchange of documents and information among the user countries so that trends can be mapped, data on diversion and smuggling routes devised, and other manifestations of these criminal acts established, in order to control and/or prevent them.

This supposes that the information system will be accessible to law enforcement authorities nationally, bilaterally, and regionally, in real time. Central authorities must also be able to remain in constant contact, in real time, to more effectively tackle offenses resulting from inadequate control.

By strengthening the indicators for gauging the distribution of medicines subject to "special control"8 and producing data and statistics that reflect the status of the inappropriate or illicit use of these substances, the system could include an information component that scientifically determines whether or not there are substances that are not used for scientific or pharmaceutical purposes and hence should not remain in the licit market of raw materials.

As a starting point, and considering that Colombia controls the pharmaceuticals industry exclusively through the Ministry of Health National Narcotics Fund, it is suggested that the Commission evaluate the information system and data-collection procedures that the Fund has been developing and implementing in producing reports, documents, and empirical evidence that facilitate the design, execution, and evaluation of public policy (national) on handling controlled medicines, their raw materials and precursors, and the so-called synthetic or designer drugs, in order to make it hemispheric in scope, with the additional components set forth herein.

The Government of Colombia is convinced that the growing problem of the diversion and smuggling of specially-controlled medicines, as well as their raw materials, across borders and through ports, containerized cargo, and customs-free areas hinders the thorough control of these substances. As a result, it feels that the information system could help to reveal trends in their diversion and smuggling, which would help to both strengthen the control and coordination capacity of national agencies and adopt measures that help to prevent and reduce this problem through bilateral and multilateral cooperation.

7 In this regard, see point 26 in the Anti-drug Strategy in the Hemisphere.

8 In Colombia, this is done by the National Narcotics Fund.